IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
ATLANTA DIVISION

FEDERAL TRADE COMMISSION,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CIVIL ACTION NO.:**
	)	**1:04-CV-3294-CAP**
	)	
NATIONAL UROLOGICAL GROUP, INC., et al.,	)	
	)	
	)	
Defendants.	)	

DEFENDANTS' MOTION FOR INTERLOCUTORY APPEAL OF THE COURT'S MAY 11, 2012 AND AUGUST 7, 2012 ORDERS, OR IN THE ALTERNATIVE, MOTION FOR MEDIATION

COME NOW the Contempt Defendants, Hi-Tech Pharmaceuticals, Inc. ("Hi-Tech") and Jared Wheat ("Wheat") (collectively, the "Contempt Defendants"), by and through their respective undersigned counsel of record, and file this "Motion for Interlocutory Appeal, or, In the Alternative, Motion for Mediation" as follows:

I. THIS COURT SHOULD CERTIFY ITS ORDERS FOR AN INTERLOCUTORY APPEAL

On May 11, 2012, this Court issued an order in which it held that the Defendants could rely only on a randomized, double-blind, placebo-controlled clinical trial of a product or an exact duplicate thereof when making weight loss claims about that product. (Doc. 390 at 8.) On August 7, 2012, the Court denied Contempt Defendants' Motion for Reconsideration (Doc. 396), holding, among other things, that Defendants were precluded from using any definition of "competent and reliable scientific evidence" for purposes of the contempt proceeding other than that to which Dr. Aronne testified. (Doc. 422 at 17.) In those two orders, the Court has decided a "controlling issue of law" on which there is "substantial ground for difference of opinion," and an appeal from the orders will "materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b); *see McFarlin v. Conseco Svcs., LLC,* 381 F.3d 1251, 1253 (11th Cir. 2004). Contempt Defendants therefore request that the Court issue an order certifying the orders as such and allowing an immediate appeal.

First, the Court's holding that Contempt Defendants are precluded from using any standard of "competent and reliable scientific evidence," other than double-blind, placebo-controlled clinical trials, despite that the Court's definition was not within the four corners of the original Injunction and that the Court's definition is contrary to federal laws and regulations, undoubtedly is a controlling

issue of law in this case. *See McFarlin*, 381 F.3d at 1259. The questions are purely legal: whether public policy trumps the actual wording of an injunction and whether the Court imposed a standard on Defendants that is contrary to federal law? Moreover, the holding decides much of the case. Contempt Defendants did not read the Court's injunction in the same manner that the Court does and hence did not use the standard that the Court has held applicable.

Second, there is substantial ground for difference of opinion on the Court's ruling. Contempt Defendants employed an attorney who specializes in advertising law, and that attorney read the Court's Injunction differently. More importantly, an administrative law judge for the FTC, an arbiter who handles nothing but cases involving the FTC, read the Court's Injunction and Summary Judgment Decision in the same manner as Contempt Defendants. *See Matter of Pom Wonderful, LLC*, FTC Docket No. 9344 at 239, 2012 WL 2340406, 2012 FTC LEXIS 106 (F.T.C. May17, 2012), available at http://www.ftc.gov/os/adjpro/d9344/120521pomdecision.pdf. That court, like Defendants, read the Court's Summary Judgment Decision (which the Court uses to interpret the Injunction) to hold that "the erectile dysfunction claims *made in that case* required well-designed, placebo-controlled, randomized, double-blind clinical trials." *Id.* (emphasis added). It did not read this Court's order as requiring that standard for all claims made about all products.

The Court relies on *SEC v. Goble*, 682 F.3d 934 (11th Cir. 2012), to hold that, although the definition of "competent and reliable scientific evidence technically lies 'outside the corners' of the Injunction," the Court did not err in incorporating Dr. Aronne's interpretation into the Injunction. (Doc. 8-9.) *Goble*, however, stands for precisely the opposite conclusion. There, the Eleventh Circuit stated that a court's equitable power was broader and more flexible where the public interest is involved, *Goble*, 682 F.3d at 952, but it went on to hold that the injunction in question did not comply with Fed. R. Civ. P. 65(d) and hence was invalid precisely because the defendant was forced to look outside the four corners of the injunction. *Goble*, 682 F.3d at 952. That the Contempt Defendants' attorneys may have disagreed as to the meaning of the Injunction does not put Defendants on notice of what is prohibited. Instead, it highlights the very problem of forcing Defendants to look outside the four corners of the injunction to determine what conduct is prohibited. *See, e.g., Int'l Longshoremen's Ass'n, Local 1291 v. Philadelphia Marine Trade Ass'n*, 389 U.S. 64, 76, 88 S.Ct. 201, 208 (1967) ("potent weapon" of judicial contempt to be used only when injunction clearly specifies prohibited conduct).

In addition, as Defendants have previously argued, under federal statutes, dietary supplements, like those produced by the Contempt Defendants, are regulated as a subset of foods, as opposed to drugs. 21 U.S.C. § 321(ff)(1). Thus,

unlike drugs, dietary supplements are *legally presumed* to be safe. *See* 21 U.S.C. § 342(f)(1)(A) (dietary supplements cannot be removed from the marketplace without the FDA first proving adulteration). As a result, dietary supplement manufacturers are not required to submit their products to pre-market clinical testing and scientific review for safety or efficacy. *See* 21 U.S.C. § 331(v) and 350b(c). Moreover, manufacturers of dietary supplements are permitted to make certain claims regarding the benefits of their products without prior FDA approval so long as the claim is based upon "substantiation" that is "truthful and not misleading." 21 U.S.C. § 343(r)(6).

Finally, an appeal on this issue will materially advance the termination of this litigation. If the Court's holding that Contempt Defendants are limited to using double-blind, placebo-controlled clinical trials to support its advertising claims prevails on appeal, then the primary questions remaining are whether Defendants acted in good faith and whether sanctions are appropriate. On the other hand, if the Court of Appeals reverses the Court, determining sanctions may never be required. Simply put, this is not a case where the same issues would remain regardless of how the Court rules. *See McFarlin*, 381 F.3d at 1259 (citing cases). To the contrary, waiting for the Court of Appeals to make that decision one way or the other only prolongs the litigation.

For the foregoing reasons, this Court should certify its orders appealable under 28 U.S.C. 1292(b).

II. IN THE ALTERNATIVE, THE COURT SHOULD REFER THE CASE TO A MAGISTRATE JUDGE FOR MEDIATION

As discussed above, Contempt Defendants concede that the advertising claims at issue were not all based on random, double-blind, placebo-controlled clinical trials. If the Court will not certify its orders for an interlocutory appeal, the primary issues remaining in the case are whether Defendants acted in good faith reliance upon advice of counsel and whether sanctions are appropriate. Defendants believe that referral of the case to a Magistrate Judge for mediation is the most expeditious manner in which to resolve those issues. Therefore, pursuant to 28 U.S.C. § 636(c) and L.R. 73.1A, Defendants request this Court to refer the case to a Magistrate Judge. *See, e.g.*, *Hunt v. Ga. Dep't of Community Affairs*, 2010 WL 5437214 (N.D. Ga. 2010).

III. CONCLUSION

For the foregoing reasons, the Contempt Defendants respectfully submit that the Court should certify its May 11 and August 7, 2012 Orders for an interlocutory appeal pursuant to 28 U.S.C. § 1292(b). In the alternative, it should refer the case to a Magistrate Judge for mediation.

Submitted this 17th day of August 2012.

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CERTIFICATION PURSUANT TO LOCAL RULE 7.1(D)

Pursuant to Local Rules 5.1(C) and 7.1(D), I hereby certify that this memorandum of law was prepared in Microsoft Word using 14-point Times New Roman font.

Respectfully submitted this 17th day of August, 2012.

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